ORAL

STATEMENT OF

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BEFORE THE HOUSE OF REPRESENTATIVES

COMMITTEE ON OVERSIGHT AND

GOVERNMENT REFORM

HEARING: "SAFE AND AFFORDABLE BIOTECH DRUGS – THE NEED FOR A GENERIC PATHWAY"

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Good morning Chairman Waxman and Members of the Committee. I want to thank you for the invitation and the opportunity to present to you this morning on this very important topic to our industry and for the general public. I am Ganesh Venkataraman, co-founder and Senior Vice President of Research at Momenta Pharmaceuticals.

I am pleased to come before you today to discuss the scientific issues behind the need to create an abbreviated regulatory approval process for generic biologics (which are defined as follow-on protein products in Dr. Woodcock's testimony). The other terms that I use are defined in the written testimony that we are submitting for the record.

Mr. Chairman, I am a chemical engineer by training, with specific expertise in bioprocess engineering, protein structural characterization, and analytic and quantitative methods for characterizing complex mixtures. While at MIT, I, with Drs Sasisekharan and Langer, developed a novel analytical technology platform that enables characterization of complex mixtures. With this platform, and with core science and leadership at MIT, we founded Momenta. We develop novel drugs and generic versions of complex products. We use cutting edge science to develop affordable and safe generic versions of these products.

Momenta has a strong interest in ensuring that Congress acts this year. We believe our company's experience demonstrates that the science is available today and continues to evolve to enable generic versions of complex mixture products.

In my written testimony, I focused on 5 major issues that I will discuss today.

1. Point 1: Complex biologic products can be thoroughly characterized.
   - Not all biologic products are the same. When we discuss the characterization challenges, we must keep in mind this *continuum of complexity*. Analytical technologies are here today to characterize less complex biologics, and approaches like ours, and others, are actively being developed for those that are more complex. In my testimony, I highlight how our technology is applied to heparins. While heparins are not biologics, it validates how complex mixtures can be characterized.

2. Point 2: With such product characterization, Generic companies will be able to design and control the manufacturing process to reproducibly make biologic drugs with the same quality as the branded companies.
   - The manufacturing process for biologic drugs does not occur in a random, or uncontrolled "system". These living cells are highly specialized systems which in a careful, and very controlled manner, produce the final product. Scientific advances in analytical technologies, available to the generic as well as the branded companies, allow one to link process parameters to final product. It is possible and absolutely critical that generic companies build and maintain this same level of process knowledge.

3. Point 3: Clinical studies (ranging from small scale PK to clinical outcome studies) should be used to address residual uncertainty, answering relevant scientific questions. Traditional empirical, or full scale clinical trials must not be a requirement for approval in all cases.
   - While FDA may require full scale trials for approval of some biologics, others, that have increased level of characterization data, should require significantly reduced clinical testing.
   - We believe the FDA is well equipped to work with applicants to determine the degree of testing necessary and define the characterization and trial requirements.

4. Point 4: Biologic drugs can be designed to be interchangeable.
   - Interchangeability is an important public health objective and products need to be designed and proved to be interchangeable. It is well within reach in the near term for a number of products. This can be done through thorough characterization, and/or through the appropriate combination of characterization and clinical trials.

5. Point 5: Patient Safety and Product Quality will not be jeopardized.
    - We should hold the entire industry, branded and generic alike, to the highest scientific standards, and rely on the expertise of FDA's scientific staff (which will approve, and oversee the marketing of innovator and generic biologics).

In closing, Mr. Chairman, there is an opportunity to drive continued scientific innovation by creating a forward-looking regulatory system, which balances the respective roles that characterization and clinical data should play. FDA has to be given the opportunity to make decisions around comparability versus interchangeability based on the science presented to them. If legislation does not allow for such a pathway today, scientific innovation from technology companies like ours and many others will be stifled, and access to more affordable choices will be denied.

I hope that my perspectives will be instructive to this debate. I am confident that these efforts under your leadership will be a key contributor to increasing access to safe, effective, and affordable medications to patients in need. I thank you again for the opportunity to submit testimony and look forward to answering any questions you may have.